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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/143,828	08/31/1998	ANDERS BERKENSTAM	10806-65	4054

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
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GROTON, CT 06340

EXAMINER	
PAK, MICHAEL D	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

HC

Office Action Summary	Application No.	Applicant(s)	
	09/143,828	BERKENSTAM ET AL.	
	Examiner	Art Unit	
	Michael Pak	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,13,16,17,51,53 and 81-89* is/are pending in the application.

4a) Of the above claim(s) *81-86* is/are withdrawn from consideration.

5)☒ Claim(s) *2,51 and 53* is/are allowed.

6)☒ Claim(s) *1,13,16,17 and 86-89* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5-12-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Response to Amendment

1. Amendment filed 12 May 2005 has been entered. Claims 1-2, 13, 16-17, 51, 53, and 81-89 are pending. Claims 3-12, 14-15, 18-50, 52, and 54-80 have been cancelled. Claims 81-89 are newly submitted claims.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Applicant's arguments filed 12 May 2005, have been fully considered but they are not found persuasive.

4. Newly submitted claims 81-86 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claims 81-86 are drawn to Group V of the restriction mailed October 4, 2000.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 81-86 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

5. This application contains claims 81-86 drawn to an invention nonelected with traverse in restriction mailed October 4, 2000. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

6. Claims 16 and 87-89 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recite "production of producing" whose term is not clear to one of skill in the art. The term is confusing and it is not clear what the term means.

Claims 87-89 recite the term "NR1I2 receptor" whose metes and bounds are not clear because the compound is identified by name alone. Names of compounds can change over time and the term is not an art recognized term to one of skill in the art. It is not clear when a polypeptide is an NR1I2 receptor or is not a NR1I2 receptor. It is not clear when a receptor is human or not human receptor because the polypeptide is described by name alone.

Claims 87-88 recite the term "DNA-binding domain" and "ligand-binding domain" whose metes and bounds are not clear because there is no specific art recognized region for these domains. Depending on the individual skilled artisan and particular alignment that is performed the domains can vary from longer to shorter from one artisan to another's comparison. Thus, the metes and bound of the term is not clear.

7. Claims 87-89 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicants indicated that the newly submitted claims are supported by the original claims and specification but did not point to specific claims or specification pages for support. The examiner could not find support for the claims. The specification does not provide support for the generic claim language of claims 87-88. The specification does not provide support for the "71% sequence identity to SEQ ID NO:2". The specification referral to "71% sequence identity" is with DBD of xONR1 on page 4 of the specification.

8. Claims 87-88 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 87 and 88 encompass "human NR1I2 receptor polynucleotide" which is described by name alone without specific structure or function. Claim 89 recite a nucleic acid encoding a polypeptide with 71% identity with SEQ ID NO:2 with function of a polypeptide is a NR1I2 receptor. However, one skilled in the art cannot envision all

the various species of "human NR1I2 receptor polynucleotide" and "a nucleic acid encoding a polypeptide with 71% identity with SEQ ID NO:2 with function of a polypeptide is a NR1I2 receptor". The specification discloses the specific species of SEQ ID NO:2 and the claims encompass a large number of species which cannot be envisioned and whose function is not specifically defined. *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification. Thus, the genus of polycucleotide structure cannot be envisioned.

9. Claims 87-89 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated cells transfected or transformed with an expression vector, does not reasonably provide enablement for an isolated cell comprising nucleic acid which is not contained in a vector. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The first paragraph of § 112 requires that the patent specification enable "those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" Genentech, Inc. v. Novo Nordisk AIS, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)); see also In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). ("[T]he scope of the claims must bear a reasonable

correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art."). Whether making and using the invention would have required undue experimentation, and thus whether the disclosure is enabling is a legal conclusion based upon several underlying factual inquiries. See In re Wands, 858 F.2d 731, 735, 736-37, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir. 1988). As set forth in Wands, the factors to be considered in determining whether a claimed invention is enabled throughout its scope without undue experimentation include the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Likewise, in Amgen Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991), the court affirmed the holding of invalidity of claims to analogs of the EPO gene under § 112 for lack of enablement where applicants had claimed every possible analog of the EPO gene but had disclosed only how to make EPO and a very few analogs. "[D]espite extensive statements in the specification concerning all analogs of the EPO gene that can be made, there is little enabling disclosure of the particular analogs and how to make them .... There may be many other genetic sequences that code for EPO-type products. Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them." Id., 927 F.2d at 1213-14, 18 USPQ2d at 1027.

Claims 87 and 88 encompass "human NR1I2 receptor polynucleotide" which is described by name alone without specific structure or function. Claim 89 recite a nucleic acid encoding a polypeptide with 71% identity with SEQ ID NO:2 with function of a polypeptide is a NR1I2 receptor. However, one skilled in the art cannot make and use a polynucleotide whose structure is specifically defined or the function is not specifically defined. The state of the art is such that one skilled in the art called the same protein with SEQ ID NO:2 structure SXR (Evans et al., US 6,756,491, column 13-16). The foreign priority SE 9703745-1 and the prior parent applications 60/067,373 do not disclose the function of the orphan receptor and the function was disclosed in foreign priority SE 9801148-9. The amount of direction provided in the specification is limited to what is practiced by one skilled in the art, which is the nucleic acid encoding a SEQ ID NO:2. One skilled in the art would require empirical experimentation in order to determine how to make and use a nucleic acid whose structure is not limited without function. One skilled in the art would require empirical experimentation in order to determine how to make and use a nucleic acid whose function is not specifically defined. Such experimentation is unpredictable and requires undue experimentation. Therefore, based on the above Wands analysis, a preponderance of the evidence supports a conclusion that one skilled in the art would not have been enabled to make and use the claimed invention without undue experimentation.

Priority

10. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, the applications upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-2, 13, 16-17, 51, 53, and 87-89 of this application. See MPEP 706.02. Claims rejected above under 35 U.S.C. 112 does not receive benefit of priority for the reasons set forth in the above rejection. Claims 1-2, 13, 16-17, 51, 53, and 87-89 receive priority for the utility and enablement of the receptor for the foreign priority SE 9801148-9 but not for the prior parent applications 60/067,373 and SE 9703745-1 because they do not disclose the function of the orphan receptor.

Claim Rejections - 35 USC § 102

11. Claims 1-2, 13, 16-17, and 87-89 are rejected under 35 U.S.C. 102(e) as being anticipated by Evans et al.(US 6,756,491).

The reason for the rejection has been set forth in the previous office action.

Evans et al. discloses nucleic acid encoding steroid X receptor (SEQ ID NO:2) which has 100% amino acid sequence identity with the claimed SEQ ID NO:2 (column 3-6). Evans et al. discloses vectors and cells comprising the nucleic acid and the method of producing the protein with the transfected cell (columns 9-10).

Applicant argue that Claims have priority to foreign priority SE 9703745-1 filed October 14, 1997. However, the foreign priority SE 9703745-1 did not disclose the function of the receptor at the time of the filing and is an orphan receptor which is not enabled and thus does not receive priority.

12. Claims 2, 51 and 53 are allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (571) 272-0879. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael D. Pak

Michael Pak
Primary Patent Examiner
Art Unit 1646
20 July 2005